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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/605,054	06/28/00	CHARIOT M	P62285US1

000136 HM22/1011
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EXAMINER	
BERMAN, A	
ART UNIT	**PAPER NUMBER**
1619	3

DATE MAILED: 10/11/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No. 09/605,054	Applicant(s) CHARIOT ET AL.	
	Examiner Alysia Berman	Art Unit 1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☒ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☒ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 1 .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other: .

DETAILED ACTION

1. Receipt is acknowledged of the preliminary amendment filed 28 June 2000. Claims 1-23 are pending.

Information Disclosure Statement

2. The information disclosure statement filed on 28 June 2000 does not fully comply with the requirements of 37 CFR 1.98 because: copies of EP 0217700 and Chemical Abstracts, Vol. 107, No. 1, 1987, Abstract No. 7211 were not supplied. Since the submission appears to be *bona fide*, applicant is given **ONE (1) MONTH** from the date of this notice to supply the above mentioned omissions or corrections in the information disclosure statement. NO EXTENSION OF THIS TIME LIMIT MAY BE GRANTED UNDER EITHER 37 CFR 1.136(a) OR (b). Failure to timely comply with this notice will result in the above mentioned information disclosure statement being placed in the application file with the noncomplying information **not** being considered. See 37 CFR 1.97(i).

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. Claims 1-20 are unclear regarding exactly what constitutes the pharmaceutical formulation. Claims 1, 8 and 17 read as a pharmaceutical formulation containing mizolastine wherein the mizolastine comprises a core containing a coated tablet containing mizolastine, a fatty matrix and an organic acid. It is unclear how mizolastine, which is a specific drug, can contain a tablet containing all of these other components. Is Applicants' intent to claim a pharmaceutical formulation comprising a coated tablet comprising mizolastine, a fatty matrix and an organic acid? If so, it is suggested that the claims be rewritten to state such in clear terms.

6. Claim 18 recites the limitation "the L-tartaric acid" in line 1. There is insufficient antecedent basis for this limitation in the claim. Claim 18 depends from claim 11, which recites "an organic acid" not L-tartaric acid.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. The instant application is drawn to a coated tablet comprising

a. Mizolastine,

b. A fatty matrix (hydrogenated castor oil, hydrogenated lecithin, long-chain fatty acids, and esters of triglycerides and medium-chain fatty acids) and

c. An organic acid (maleic, tartaric, malic, fumaric, citric, lactic, adipic and succinic acids).

10. Claims 1-3, 7-11, 15, 16, 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 4,590,062 ('062) in combination with the Derwent abstract of Mosques et al, Antihistamines for the treatment of nasal congestion, Allergy, 1996, 51(31):157 (AS).

US '062 discloses a controlled and continuous release dosage form containing a matrix made from a fatty acid material or a neutral lipid (abstract). Coated tablets are taught at column 1, lines 51-53. The matrix is made of an admixture of a fatty acid consisting of 12-28 carbon atoms such as stearic acid and palmitic acid or a neutral lipid such as stearin, palmitin, castorwax (hydrogenated castor oil) and glycerides (col. 3, lines 19-40). See also column 7, line 43 to column 8, line 10 for fatty acids, lecithin and hydrogenated castor oil. US '062 teaches that vitamin C (ascorbic acid), which is an organic acid, and antihistamines are suitable biologically active materials for use in the dosage forms (col. 4, line 48 and col. 5, line 16).

The percentages and, therefore, the ratios of materials in the formulation may be varied in order to modify the release rate (col. 3, lines 56-60). Therefore, absent evidence of unexpected and superior results, the dissolution profiles as instantly claimed are not considered critical to the

invention. The reference does not teach mizolastine. Mosqes et al. teach that mizolastine tablets act as antihistamines for significant improvement of nasal flow.

Consisting essentially of limits the scope of the claim to the specified ingredients and those that do not materially affect the basic and novel characteristics of a composition. *Ex parte Davis*, supra; *In re Janakirama-Rao*, 317 F2d 951, 137 USPQ 893 (CCPA 1963). When applicant contends that modifying components in the reference composition are excluded by the recitation of "consisting essentially of", applicant has the burden of showing the basic and novel characteristics of his composition – i.e. a showing that the introduction of these components would materially change the characteristics of applicant's composition. *In re De Lajarte*, 337 F2d 870, 143 USPQ 256 (CCPA 1964). Therefore, any additional ingredients required in the prior art compositions are encompassed by the claims, absent evidence that they materially affect the basic and novel characteristics of the instant invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the tablets of US '062 and substitute mizolastine for the antihistamine as taught by Mosqes et al. with the reasonable expectation of providing an oral antihistamine. The motivation to do so stems from the art-recognized desire for improved nasal flow caused by allergic reactions and sustained, controlled release of a medicament. This is a *prima facie* case of obviousness.

11. Claims 4-6, 12-14, 17-20 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of US 4,590,062 ('062) and Mosqes et al. as applied to claims 1-3, 7-11, 15, 16, 21 and 22 above, and further in view of US 5,102,666 ('666).

US '062 and Mosqes et al. teach all the limitations of the claims as stated above. They do not teach L-tartaric acid or maleic, malic, fumaric, lactic, citric, adipic and succinic acids.

US '666 discloses a controlled release matrix composition that can be in the form of a tablet (col. 1, lines 6-13). Antihistamines are disclosed at column 7, line 7. The reference teaches that citric acid and tartaric acid are known flavorants in oral dosage forms such as tablets (col. 8, lines 6-11).

The disclosure of tartaric acid encompasses both a racemic mixture and any individual isomers. Nothing unobvious is seen in substituting one isomer for another or for the racemic mixture. It would be expected that structurally similar isomers would exhibit similar properties. Therefore, absent evidence of unexpected and superior results, the L-isomer of tartaric acid is not considered critical to the invention.

It would have been obvious to one of ordinary skill in the art at the time of the invention to prepare the composition of US '062 in combination with Mosqes et al. and add tartaric acid or citric acid as taught by US '666 with the reasonable expectation of providing a controlled release antihistamine tablet. The motivation to do so stems from the art-recognized desire for oral dosage forms with a pleasant taste. This is a *prima facie* case of obviousness.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1-23 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 24-28 of copending Application No. 09/125810. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are directed toward a coated sustained release tablet comprising mizolastine, a fatty matrix and an organic acid.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

14. Presently no claim is allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alysia Berman whose telephone number is 703/308-4638. The examiner can normally be reached on Monday through Friday from 8:30 to 4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana Dudash can be reached on 703/308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are 703/305-3704 for regular communications and 703/305-3704 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-1234.

Alysia Berman
Patent Examiner
05 October 2000

DIANA DUDASH
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